



Robert Greene Sterne Jorge A. Goldstein David K.S. Cornwell Robert W. Esmond Tracy-Gene G. Durkin Michael B. Ray Robert E. Sokohl Eric K. Steffe Michael Q. Lee John M. Covert Robert C. Millonig Donald J. Featherstone Timothy J. Shea, Jr Michael V. Messinger Judith U. Kim Jeffrey T. Helvey Eldora L. Ellison Donald B. Banowit

Peter A. Jackman Brian J. Del Buono Mark Fox Evens Vincent L. Capuano Elizabeth J. Haanes Michael D. Specht Kevin W. McCabe Glenn J. Peny Edward W. Yee Grant E. Reed Virgil Lee Beaston Theodore A. Wood Joseph S. Ostroff Jason D. Eisenberg Iracy L. Muller Jon E. Wright LuAnne M. DeSantis Ann E. Summerfield Helene C. Carlson

Cynthia M. Boucher Gaby L. Longsworth Lori A. Gordon Laura A. Vogel Bryan S. Wade Bashir M.S. Ali Shannon A. Carroll Anbar F. Khal Michelle K. Holoubek Marsha A. Rose Scott A. Schaller Lei Zhou Young Tang Christopher J. Walsh W. Blake Coblentz James J. Pohl John T. Haran Mark W. Ryglel Michael R. Malek* Carla Ji-Eun Kim Doyle A. Siever* Ulrike Winkler Bryan L. Skelton* Paul A. Calvo Robert A. Schwartzman C. Matthew Rozier Alexandra K. Pechhold

Registered Patent Agents « Karen R. Markowicz Matthew J. Dowd Katrina Yujian Pei Quach Julie A. Heider Mita Mukherjee Scott M. Woodhouse Peter A. Socarras Jeffrey K. Mills Danielle L. Letting Lori Brandes Steven C. Oppenheimer Aaron S. Lukas Gauray Asthana

Of Counsel Idward J. Kessler Kenneth C. Bass III Marvin C. Guthrie Christopher P. Wrist

*Admitted only in Maryland *Admitted only in Virginia •Practice Limited to Federal Agencies

April 23, 2007

WRITER'S DIRECT NUMBER: (202) 772-8560 INTERNET ADDRESS: RESMOND@SKGF.COM

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450 Art Unit 1614

Mail Stop Amendment

Re:

U.S. Utility Patent Application

Application No. 10/814,633; Filed: April 1, 2004 For: Solution Based Methacholine Formulations

Inventor: Van Hung Truong Our Ref: 2201.0020000/RWE

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Credit Card Payment Form (PTO-2038) in the amount of \$180.00 to cover the fee for consideration of an Information Disclosure Statement;
- 2. First Supplemental Information Disclosure Statement;
- 3. Form PTO/SB/08A (1 sheet);
- 4. Form PTO/SB/08B (1 sheet);
- 5. Copies of five (5) references (Documents FP1 and NPL18-NPL21); and
- 6. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Sterne, Kessler, Goldstein & Fox P.L.L.C.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skgf.com

Commissioner for Patents April 23, 2007 Page 2

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond Attorney for Applicant Registration No. 32,893

RWE/dab 667443_1.DOC Enclosures

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Van Hung Truong

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Appl. No.: 10/814,633

Filed: April 1, 2004

For: Solution Based Methacholine

Formulations

Confirmation No.: 7438

Art Unit: 1614

Examiner: Graffeo, Michel

Atty. Docket: 2201.0020000/RWE

First Supplemental Information Disclosure Statement

Mail Stop Amendment

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. The numbering on this First Supplemental Information Disclosure Statement is a continuation of the numbering in Applicant's Information Disclosure Statement filed on September 1, 2005 in connection with the above-captioned application. Copies of documents NPL18-NPL21 and FP1 are submitted. However, in accordance with 37 C.F.R. § 1.98(a)(2), no copies of U.S. patents and patent application publications cited on the attached IDS Forms are submitted. In addition, Document NPL22 is a website address accessible to the public and is not submitted herewith.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is

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not in issue. Applicant has listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our PTO-2038 Credit Card Payment Form which includes the amount of \$180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

All the cited documents, except Document NPL22, were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Robert W. Esmond Attorney for Applicant

Registration No. 32,893

Date:

1100 New York Assessed N.W.

1100 New York Avenue, N.W. Washington, D.C. 20005-3934 (202) 371-2600

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FIRST SUPPLEMENTAL
INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

of

(Use as many sheets as necessary)

1

Complete if Known				
Application Number	10/814,633			
Filing Date	April 1, 2004			
First Named Inventor	Van Hung Truong			
Art Unit	1614			
Examiner Name	Graffeo, Michel			
Attorney Docket Number	2201.0020000/RWE			

			U.S. PATENT DO	CUMENTS		
Examiner Cite No. 1		Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	No.'	Number-Kind Code ^{2 (If Known)}	MM-DD-YYYY	Applicant of Cited Document		
	US1					
	US2	2004/0042970 A1	03/04/2004	Basu et al.		
	US3	5,570,683	11/05/1996	Zapol, W.M.		
	US4					
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FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where	
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)			Relevant Passages or Relevant Figures Appear	T ⁶
	FP1	WO 00/62819 A	10/26/2000	Ontario, Inc.		
	FP2					
	FP3					
	FP4					
	FP5					
	FP6					<u> </u>
	FP7		-		<i>'</i>	
	FP8					$ldsymbol{ld}}}}}}$
	FP9					

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Examiner	Date	
Signature	Considered	

English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

PTO/SB/08B (07-06)

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Output for form 1449B/PTO				Co	Complete if Known		
FIDET CUDDI EMENTAL			FAI	Application Number	10/814,633		
FIRST SUPPLEMENTAL		Filing Date	April 1, 2004				
INFORMATION DISCLOSURE				First Named Inventor	Van Hung Truong		
STATEMENT BY APPLICANT (Use as many sheets as necessary)		Art Unit	1614				
		Examiner Name	Graffeo, Michel				
Sheet	1	of	1	Attorney Docket Number	2201.0020000/RWE		

		Non Patent Literature Documents	1
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
	NPL18	Bonte, F. et al., "Contribution pharmaceutique à l'exploration de l'hyperréactivité bronchique non spécifique," Ann. Pharm. Fr. 58:165-169, Paris: Masson et Cie (2000)	
	NPL19	European Search Report for European Patent Application No. 04255015.2, European Patent Office, The Hague, published October 4, 2006	
	NPL20	Pratter, M.R. et al., "Stability of Stored Methacholine Chloride Solutions: Clinically Useful Information," Am. Rev. Respir. Dis. 126:717-719, New York, NY: American Lung Association (1982)	
	NPL21	Rubinfeld, A. and Pain, M.C.F., "Perception of Asthma," <i>Lancet 7965</i> :882-884, New York, NY: Lancet Publishing Group (1976)	
	NPL22	United States Food and Drug Administration's Ingredient Guide, accessed at http://www.accessdata.fda.gov/scripts/cder/iig/index.cfm .	
	NPL23		
	NPL24	·	
	NPL25		
	NPL26		
	NPL27		

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Examiner	Date	
Signature	Considered	

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.